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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,161

Applicant(s)

TAKAHASHI ET AL.

Examiner

Leon Y Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on June 25, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the copies of English translations of the foreign documents JP 10-132817, JP 9-119932, and JP 9-72904 have not been provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

2. The information disclosure statement filed on June 25, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

3. Claims 1-10 and 21-28 are objected to because of the following informalities:

The term "at the" in line 1 of the claims should be replaced by "for the". Appropriate correction is required.

4. Claims 11-20 and 29-36 are objected to because of the following informalities:

The term "wherein" in line 1 of the claims should be replaced by "comprising".

Appropriate correction is required.

5. Claims 8, 18, 26, and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The spectrophotometer applies to a method of analyzing coloration that does not limit the immunochromatographic specimen, marker, substance produced by the marker, reactant by the marker, or colored sample in the parent claims.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claims 1-2, line 1, and 11-12, line 2, the term "immunological specimen" is confusing and indefinite. It is not clear if the specimen recited in the claims is meant as a sample or an apparatus. The term specimen is conventionally meant as a sample. For example, Webster's II New Riverside University Dictionary defines specimen as "a sample, as of tissue, blood, or urine, used for analysis and medical diagnosis." However, the term "immunological specimen" reads like it should be an apparatus or device. Thus, one of ordinary skill in the art cannot determine the metes and bounds of "immunological specimen". Applicant is invited to clarify the term as a sample or apparatus.

9. In claims 1-2, lines 2-3, and claims 11-12, line 3, the term "colored sample" is vague and indefinite as to what kind of samples are considered "colored". Applicant is invited to define the term.

10. In claim 1, line 2, and claim 11, line 7, the term "produced" is vague and indefinite as to how the "substance" in the same line is created. Is the substance produced through a reaction of the marker with other substances, or is the substance created

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exclusively by the marker alone, and by what mechanism? Applicant is invited to clarify and define the term.

11. In claims 1-2, lines 7 and 10, and 11-12, lines 10 and 13, the term "sample" is confusing and indefinite as to what it refers to. Is the sample the "colored sample" or the "immunochromatographic specimen"? Applicant is invited to clarify what the term "sample" is directed towards.

12. In claims 1-2, line 9, and claims 11-12, line 12, the term "sufficiently higher" is vague and indefinite. The specification provides a definition for the term "sufficiently higher" on page 20, lines 14-16, as meaning "that the signal from the marker by the color reaction is high to the extent that a reliable result of the qualitative or quantitative analysis is obtained." The term "sufficiently higher" is defined as a "reliable result". However, the specification does not define the term "result" and renders the definition vague and indefinite. Applicant is invited to clearly define the term "sufficiently higher".

13. The term "using" in claims 11-2, line 1, is a relative term which renders the claim indefinite. The term "using" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how the immunochromatographic specimen will be applied towards the chromatograph analyzing method.

14. The term "components" in claims 4, 14, 22, and 30, line 2, is a relative term which renders the claims indefinite. The term "components" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what cell parts are destroyed.

15. The term "coloration" in claims 11-12, line 6, is a relative term which renders the claim indefinite. The term "coloration" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how the coloration is presented (i.e. fluorescent, non-fluorescent) and correspondingly, what absorption wavelength to choose.

16. Claims 11-12 recite the limitations "the immunochromatographic specimen" in line 2 and "the colored sample" and "the analyte" in line 3 of the claims. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-3, 8-13, 18-21, 26-29, and 34-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Phillips et al (USP 4,935,346).

19. Phillips et al anticipate the instant claims by teaching a method to create and use a matrix test strip for the detection of analytes in a fluid sample. The method comprises the teaching that it is necessary to select a marker (dye) having an absorbance at a wavelength different from the wavelength at which the sample (red blood cells) absorb light (column 10, lines 32-34).

20. Regarding claims 2, 12, 21, 26-29, and 34-36, Phillips et al teach that a reaction can occur between two markers, producing a dye couple, (column 10, lines 36-39).

21. Regarding claims 3, 13, 21, and 29, Phillips et al teach that the wavelength for measuring blood is 700nm (column 10, lines 64-66).

22. Regarding claims 11-13, 18-20, 29, and 34-36, Phillips et al teach that a colored sample (blood) can be added to the specimen (column 1, lines 9-12). Furthermore, Phillips et al teach that the coloration degree is measured at an absorption wavelength specific to the coloration (column 7, lines 12-15 and 30-40).

23. Regarding claims 8, 18, 26, and 34, Phillips et al teach that the coloration degree can be measured using a spectrophotometer (column 7, lines 43-48).

24. Regarding claims 9, 19, 27, and 35, Phillips et al teach that the marker is a dye sol (column 10, lines 30-57).

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25. Regarding claims 10, 20, 28, and 36, Phillips et al teach that the analyte is a plasma protein (column 2, line 68).

26. Claims 1-3, 8-13, 18-21, 26-29, and 34-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Buechler et al (USP 5,763,189).

27. Buechler et al anticipate the instant claims by teaching a method of creating a composition of fluorescent dyes for the detection of analytes in a fluid sample. The method comprises the teaching that the absorption wavelength of a dye marker should not correspond to that of a sample (column 3, lines 38-40).

28. Regarding claims 2, 12, 21, 26-29, and 34-36, Buechler et al teach that a reaction can occur between two dye markers (column 6, lines 45-49).

29. Regarding claims 3, 13, 21, and 29, Buechler et al teach that absorption wavelengths for biological fluids, including blood, should be above 600nm (column 4, lines 41-46).

30. Regarding claims 11-13, 18-20, 29, and 34-36, Buechler et al teach that colored samples can be added to the specimen (column 2, lines 29-31). Furthermore, Buechler et al teach that the coloration degree is measured at an absorption wavelength specific to the coloration (column 4, lines 20-27).

31. Regarding claims 8, 18, 26, and 34, Buechler et al teach that the coloration degree can be measured using a spectrophotometer (column 19, lines 7-9).

32. Regarding claims 9, 19, 27, and 35, Buechler et al teach that the marker is a dye sol (column 6, lines 3-6).

33. Regarding claims 10, 20, 28, and 36, Buechler et al teach that the analyte is a plasma protein (columns 36-37, Example 17).

Claim Rejections - 35 USC § 103

34. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Claims 4-6, 14-16, 22-24, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al (USP 4,935,346) in view of Bernstein et al (USP 5,824,268).

Phillips et al reference has been disclosed above, but fails to teach a region for holding a substance which destroys cells components in the sample, and that the substance includes chloride.

Bernstein et al teach an apparatus comprising a region (absorbent material in a sample collection) to localize red blood cells to treat them with a solution containing ammonium chloride in order to lyse the cells and release the intended target cell components for specific binding with particles (in column 10, lines 41-54).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the device of Phillips et al, a component to localize cells and treat them with a solution containing ammonium chloride, as taught by Bernstein et al, in order to lyse the cells and release the intended cell targets for specific binding with particles.

37. Claims 7, 17, 25, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al (USP 4,935,346) in view of Bernstein et al (USP

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5,824,268) as applied to claims 1-2, 4-6, 11-12, 14-16, 22-24, and 30-32 above, and further in view of Chu et al (USP 5,558,834).

Phillips et al and Bernstein et al references have been disclosed above, but fail to teach a substance which destroys cell components to include nonpolar surfactants.

Chu et al teach a cell lysing solution to include nonpolar surfactants in order to destroy cells to release and capture cell components to determine the presence of specific particles (column 1, lines 14-23).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the device of Phillips et al and Bernstein et al, a cell lysing solution to include nonpolar surfactants, as taught by Chu et al, as an alternative to ammonium chloride in order to destroy cells to release and capture cell components to determine the presence of specific particles.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lee (USP 5,821,073) teaches a test to detect analytes in fluids, with labels consisting of metal and non-metal sols, metal oxides, dyes, colored particles, pigments, and enzymes.

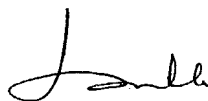
Maddox (USP 5,212,060) teaches a test strip for an immunological or chemical assay system to detect proteins, bacteria, and viruses.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

02/15/04